Application No.: 09/531,851

15. The method of Claim 12, wherein the furanose sugar of Formula II is in the β-D-configuration.

- 16. The method of Claim 11, wherein the purinergic agent is administered in an amount effective to treat vaginal dryness.
- 17. The method of Claim 12, wherein the purinergic agent of Formula II is administered in an amount effective to treat vaginal dryness.
- 18. The method of Claim 17, wherein the amount of compound of Formula II, administered to the mammal is sufficient to achieve a concentration on the cervical and/or vaginal mucosa of from about 10<sup>-7</sup> moles/liter to about 10<sup>-1</sup> moles/liter.
- 19. The method of Claim 17, wherein the amount of compound of Formula II, administered to the mammal is sufficient to achieve a daily dose of between 1 to 1000 milligrams.
- 20. A method of stimulating cervical and vaginal secretions in a mammal in need thereof by administering an effective secretion stimulating amount of a compound of P<sup>1</sup>, P<sup>4</sup>-di(uridine-5')tetraphosphate.
- 21. A method of treating a mammal with vaginal dryness by administering an effective vaginal treatment amount of a compound of P<sup>1</sup>, P<sup>4</sup>-di(uridine-5')tetraphosphate. --

#### REMARKS

## **The Amendments**

Applicant is canceling Claims 1-10 and adding new Claims 11-21 such that new claims in this application are drawn to the same patentable invention claimed in another patent to provoke an interference.



Attorney's Bocket No. 03678.0028.US04

Application No.: 09/531,851

Claim 11 is supported, for example, by page 1, lines 9-12; page 2, lines 25-27; page 4, line 24 through page 5, line 1; and Claim 1 as filed.

Claim 12 is supported by page 5, lines 4-7, and Claim 1 as filed.

Claim 13 is supported by Claim 2 as filed.

Claim 14 is supported by Claim 3 as filed.

Claim 15 is supported by Claim 5 as filed.

Claim 16 is supported by Claim 6 as filed.

Claim 17 is supported by Claim 6 as filed.

Claims 18 and 19 supported by Claims 8 and 9 as filed, respectively.

Claim 20 is supported by page 4, lines 18-21 and Claim 1 as filed.

Claim 21 is supported by page 4, lines 18-21 and Claim 6 as filed.

## **Identification of the Patent**

On September 25, 2001, U.S. Patent No. 6,294,188 (hereinafter, the '188 Patent) was issued to Aviana BioPharm Inc. The patent is entitled METHODS INVOLVING CHANGING THE CONSTITUTIVE AND STIMULATED SECRETIONS OF THE LOCAL REPRODUCTIVE SYSTEM OF WOMEN. Applicant requests that an interference be declared between the instant application and the '188 Patent. A copy of the '188 Patent is enclosed herewith.

### **Proposed Counts**

#### Count 1.

A method of affecting the amount of or properties of the cervical and vaginal mucosa comprising administering an effective amount of a composition comprising a compound selected from the group consisting of histamine receptor antagonists and purinergic agents to an individual in need of treatment thereof.

Patent Claim 1 is essentially identical to Count 1 except that Patent Claim 1 additionally has a wherein clause. Patent Claim 1 is designated to correspond to Count 1. Patent Claims 2-16 are dependent upon claim 1; Patent Claims 2-16 are designated to correspond to Count 1.

Application Claim 11 is almost identical to Count 1 except that Application Claim 1 does not include histamine receptor antagonists. Application Claim 11 is designated to correspond to Count 1. Application Claim 12 recites a species (Formula II) of purinergic agents; Application Claim 12 is designated to correspond to Count 1. Application Claims 13-19 are dependent upon Claim 12; Application Claims 13-19 are designated to correspond to Count 1. Application Claims 20 and 21 are narrower in scope of Count 1; Application Claims 20 and 21 are designated to correspond to Count 1.

## Count 2.

A method of affecting the amount of or properties of the cervical and vaginal mucosa comprising administering an effective amount of a composition comprising a compound selected from the group consisting of histamine receptor antagonists and purinergic agents to an individual in need of treatment thereof, wherein the compound is administered in an amount effective to treat vaginal dryness.

Patent Claim 12 is essentially identical to Count 2 except that Patent Claim 12 additionally has a wherein clause. Patent Claim 12 is designated to correspond to Count 2.

Application Claim 16 is almost identical to Count 2 except that Application Claim 16 does not include histamine receptor antagonists. Application Claim 16 is designated to correspond to Count 2. Application Claim 17 is directed to a species (Formula II) of a purinergic agent; Application Claim 17 is designated to correspond to Count 2. Application Claims 18-19 are dependent upon Claim 17; Application Claims 18-19 are designated to correspond to Count 2. Application Claims 21 recites a species (P¹, P⁴-di(uridine-5')tetraphosphate) of punergic agents; Application Claim 21 is designated to correspond to Count 2.

Applicant submits that Count 1 to a genus, a method of affecting the amount of or properties of the cervical and vaginal mucosa, and Count 2 to a species, a method of treating vaginal dryness, are both properly included in the interference because Applicant believes that the species is patentable over the genus, even though the genus might not be patentable, given the species.

# Compliance with 37 C.F.R. § 1.607(a)

This request for interference complies with the requirements of 37 C.F.R. § 1.607(a):

- (1) The patent is identified as U.S. Patent No. 6,294,188;
- (2) At least one proposed count has been presented;
- (3) Patent Claims 1-16 are designated to correspond to Proposed Count 1, Patent Claim 12 is also designated to correspond to Proposed Count 2;
- (4) Applicant's Claims 11-21 are designated to correspond to Proposed Count 1, Applicant's Claims 16-19 and 21 are also designated to correspond to Proposed Count 2;
- (5) Applicant has applied the terms of application claims,
  - (i) corresponding to the count, and
  - (ii) not previously in the application to the disclosure of the application; and
- (6) The claims presented in the application are present in the application within one year after the issue date of the '188 Patent.

## Statement under 37 C.F.R. § 1.608 (a)

The effective filing date of this application is three months or less after the effective filing date of the '188 Patent. Applicant submits herewith a statement under 37 C.F.R. § 1.608 (a) asserting that there is a basis upon which the Applicant is entitled to a judgment relative to the patentee.

Attorney's Bocket No. 03678.0028.US04 Application No.: 09/531,851

The Commissioner is hereby authorized to charge any fee or underpayment, or credit any overpayment, to the Howrey & Simon Deposit Account No. 08-3038 for any matter in connection with this communication, including any fee for extension of time which may be required.

Respectfully submitted,

Date: November 28, 2001

Albert P. Halluin (Reg. No. 25,227) Viola T. Kung (Reg. No. 41,131)

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